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EXAMINER
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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Paper No. 29

Application Number: 08/897,455
Filing Date: July 22, 1997
Appellant(s): Ulrich Stache et al.

Frank E. Caffoe and Steven J. Scott
For Appellant

EXAMINER'S ANSWER

This is in response to appellant's brief on appeal filed October 1, 1999.

(1) Real Party in Interest

A statement identifying the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

(3) Status of Claims

The statement of the status of the claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Invention

The summary of invention contained in the brief is correct.

(6) Issues

The appellant's statement of the issues in the brief is correct.

(7) Grouping of Claims

Appellant's brief includes a statement that claims 1, 4-5 and 7-10 do not stand or fall together and provides reasons as set forth in 37 CFR 1.192(c)(7) and (c)(8).

(8) Claims Appealed

The copy of the appealed claims contained in the Appendix to the brief is correct.

(9) Prior Art of Record

The following is a listing of the prior art of record relied upon in the rejection of claims under appeal.

4,655,971	PAGE et al.	4-1987

(10) Grounds of Rejection

The rejection of claim 7 under 35 USC § 112, second paragraph is withdrawn.

The rejection of claims 1-2 and 4-5 under 35 USC § 103(a) over Annen et al. ('763) made in Paper No. 14 stands withdrawn.

The following ground(s) of rejection are applicable to the appealed claims:

Claims 1, 4-5 and 7-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Page et al. ('971).

Page et al. generically teach 17,21-dicarboxylic esters of 4-pregnen-3,20-dione having either an oxo, halogen or a hydroxyl group in the 11-position and substituents in the 6, 9 and 16 positions which include those recited by the claimed invention. The reference teaches the compounds may also contain a double bond in the 1-position (col. 1, lines 1-55; col. 8, lines 47-59) and the use of the compounds in the treatment of corticosteroid-responsive dermatosis (col. 8, lines 30-41).

The instant claims differ from the reference by reciting specific species not exemplified by the reference, that is, claimed compounds wherein R(1) is a phenyl which may be substituted as indicated by the claimed invention. However, the generic disclosure of Page suggests most of the substituents of the claimed "Markush" structure including the claimed aralkyl ester group attached to the 21-position. Page discloses compounds of formula (I) wherein R_5 is OC(O)-R", wherein R' is an alkyl group of 1 to 16 carbon atoms, a phenyl group or an aralkyl group of 7 to 8 carbon atoms (i.e., -$(CH_2)_{1-2}$-phenyl). Applicant's claimed compound defining R(1) as a phenyl group is thus within the scope of the disclosure of Page et al. The motivation to make the claimed compounds is based on the desire to make additional compounds useful in the treatment of corticosteroid-responsive dermatosis as taught by the prior art.

(11) Response to Argument

Applicant argues that the prior art does not provide motivation to make the claimed invention, although, applicant agrees that Page et al. generically teach the side chain in the 21-position as recited by the present invention. Applicant argues that the prior art lacks motivation to make the claimed compounds because, according to applicant, such a derivation could "only have been made by an unguided simultaneous

selection of a high number of independent variables from the Page disclosure". Applicant also argues (1) that the present situation is analogous to the obviousness issues decided in *In re Baird* and *In re Jones* and (2) that the prior art as a whole, including previously cited references, show that the state of the art did not motivate modifications of compounds of Page et al. Applicant's arguments were not persuasive for the following reasons.

Applicant's arguments center around the working examples of Page et al. However, as indicated in previous Office Actions, a reference is evaluated based on what it teaches one having ordinary skill in the art and not on the exemplified compounds shown in the prior art.

Page et al. generically teach the claimed compounds and their use in the treatment of corticosteroid-responsive dermatosis. It is noted that the generic disclosure of Page et al. teach most of the substituents of the claimed "Markush" structure. It is also noted that the method of use of the compounds and, thus, pharmaceutical composition(s) taught by the prior art are similar to those recited by the claimed invention. The reference also specifically exemplifies compounds which differs from the claimed compounds only by the substituents shown in the 21-position (see examples 9 and 19). The difference between the compounds of examples 9 and 19 exemplified by Page et al. is the presence of an acetate group or a hydroxyl in the 21-position, respectively. However, Page et al. teach an equivalence between both

groups and an ester group having an aralkyl moiety (i.e., -$(CH_2)_{1-2}$-phenyl) as recited by the claimed invention (see Page et al., col. 1, lines 17-55). Thus, based on the disclosure of Page et al. as a whole, it would have been obvious to one having ordinary skill in the art at the time of the present invention, to make the compounds of examples 9 and 19 of Page having a -$(CH_2)_{1-2}$-phenyl group in the 21-position instead of the hydroxyl or acetate group as exemplified by Page et al. with reasonable expectation that the compounds produced would be useful in treating dermatosis as taught by the reference. Applicant's argument of unguided simultaneous selection of a high number of independent variables from the Page disclosure fails because of the examples given by Page as indicated above. The ordinary artisan would have to make only **one** change to the exemplified prior art compound(s) (i.e., replacing a hydroxyl or acetate group for a -$(CH_2)_{1-2}$-phenyl group) and said modification is taught by Page et al.

Applicant also argues that the present situation is analogous to the obviousness issues decided in *In re Baird* and *In re Jones*. The examiner disagrees because, in both of the cited cases, the claims were drawn to a particular compound and not to a Markush group as presently claimed. The issue of the present application is not one of choosing a specific compound from the many compounds encompassed by the prior art. The issue is selecting a generic group of compounds from amongst the genus taught by the prior art. In other words, the claimed Markush group was created by deleting certain members of the Markush group taught by Page et al. However, the

claimed Markush group is supported by Markush group taught by Page et al. The motivation to make the claimed compounds is based on the teachings by the reference that modification of the exemplified compounds as recited by the Page et al. would result in claimed compounds which would useful in treating dermatosis as taught by reference. The motivation to make the said modification is in essence a desire to make additional compounds taught by Page et al. useful in treating dermatosis.

It is also noted from the present specification that applicant intended the inclusion of compounds having other than an aralkyl ester group in the 21-position (see especially examples 3-5 on pages 21-22 of the present specification).

Applicant's argument and inclusion of other prior art is noted. However, the references referred to in applicant's brief do not teach the equivalence of an aralkyl ester group and other acyl groups attached to the 21-position as taught by Page et al. and, thus, are not relevant to the issue of patentability of the presently claimed compounds.

In summary, the present claims are drawn to a generic group of compounds embraced by the disclosure of Page et al. Both the present invention and the cited prior art teach the use of the compounds in treating dermatosis. The motivation to modify the exemplified prior art compound(s) in order to produce the presently claimed compounds is based on the desire to make additional compounds taught by Page et al. useful in the treatment of dermatosis. The motivation is also based on the teachings of

equivalence between the exemplified group and the aralkyl group (i.e., -$(CH_2)_{1-2}$-phenyl) by Page et al.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

BB
November 16, 1999

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